REMARKS

Claims 1-118 are in this application. In the Office Letter of 2 June 2004, the Examiner acted only on claims 61-118. In response to several telephone calls to Examiner Mercader and Supervising Examiner Sykes, commencing on 9 July 2004, Ms. Mercader called on 2 August 2004 and left a message that claim 1-60 required no new consideration, that everything in the 2 June 2004 Action applied equally to claim 1-60, and did not start a new three-month response period.

While some of the claims have been amended for clarification, Applicants respectfully traverse all of the grounds for rejection advanced by the Examiner.

The Double Patenting Rejection

All of the claims have apparently been rejected on the ground of the judicially created doctrine of obviousness-type double patenting over claims 1, 2 and 5 of US patent 6,496,713, which patent is a continuation-in-part of the present application. This ground of rejection is respectfully and specifically traversed.

The '713 patent only claims the use of a water bag which is attached to a rigid barrier, the barrier being spaced from the patient by the water bag, in a larger system. However, a significant distinguishing aspect is that the '713 patent is for screening "for the presence of a ferromagnetic *foreign body*" (emphasis added) in a region of interest (the human eye, for example). Its purpose is to determine localized areas of increased susceptibility (col. 3, line 15). It does not measure

magnetic susceptibility variations *in selected body tissue* by measuring magnetic susceptibilities of that tissue. So it has an entirely different purpose. Further, claim 1, as revised, requires the barrier and the patient to remain stationary with respect to each other and that the volume of the water bag remain constant, while the instrument moves with respect to the barrier and the patient.

These claim differences of method claim 1 are substantive and do not "constitute obvious alternate variations and groupings," as stated by the Examiner.

With regard to the claims depending from claim 1, the '713 patent does not claim, in combination:

- Alternating current to the applied field coil (claim 2);
- Means for displacing the instrument (claim 3);
- The displacement being between about one to six inches (claim 4);
- The displacement means operating between about 0.5 to 10.0 Hz (claim 5);
- The data output corresponding to magnetic susceptibility variations indicates concentrations of paramagnetic material in the body tissue (claim 6) ('713 does not deal with paramagnetic material);
- The paramagnetic material is iron and the tissue is liver (claim 7);
- The resolution of measurements of concentrations of iron correspond to about 30 micrograms per milliliter (claim 8); or
- The positioning step functionally replaces the irregular shape of the patient's body with a volume of material having similar magnetic susceptibility to body tissue, the volume of material having a surface of constant shape defined by the barrier (claim 9).

Independent claim 10 defines apparatus for performing the claim 1 method and is for a similar purpose, "to determine a compositional state in the body." (Note that '713 does not determine a compositional state in the body tissue by measuring magnetic susceptibility variations in the body

tissue of interest, but only determines whether or not a *ferromagnetic foreign body* is present in the body.) The relationship of the bag, barrier, patient, and detector assembly in claim 10 are as stated above with respect to claim 1 and are not claimed in the '713 patent.

Further, with respect to the claims depending from claim 10, the '713 patent does not claim, in combination:

- Using an AC signal generating source (claim 11);
- Means for processing signals comprises a processor for analyzing the signals from the magnetic sensor (claim 12);
- Output means for displaying paramagnetic material concentration (claim 13)('713 does not deal with paramagnetic material);
- The paramagnetic material is iron (claim 14);
- The field coil is designed to create a first zone of finite magnetic field within a selected region of the body, and a second zone of substantially zero magnetic field outside the selected region, with the at least one magnetic sensor positioned with the second zone (claim 15);
- The at least one magnetic sensor attaches to a central region relative to the applied field coil (claim 16);
- The at least one magnetic sensor attaches as in claim 16 and the applied field coil is attached to a planar substrate (claim 17);
- The applied field coil comprises at least two parallel flat coils and a connecting circuit causing current to flow in identical directions at corresponding locations in the flat coils, stimulating parallel uniform sheets of current (claim 18);
- The applied field coil comprises at least two concentric coils and a connecting circuit causing current to flow in opposite directions, canceling the effects of a magnetic current caused by current flowing through the applied field coil at a central region of the at least two concentric coils (claim 19);
- The detector assembly is multiple stacked applied field coils (claim 20);
- The at least one magnetic sensor is a magnetoresistive sensor (claim 21);

- The at least one magnetic sensor is a flux gate sensor (claim 22);
- The at least one magnetic sensor is a magnetoinductive sensor (claim 23);
- The at least one magnetic sensor is part of a Wheatstone bridge sensing circuit (claim 24);
- Magnetic sensor compensating electronics and a feedback coil around the magnetoresistive sensor for the purposes stated (claim 25);
- Means for oscillating the detector assembly (claim 26);
- The detector assembly is in a housing structure for positioning it in proximity to a surface of a human body, the oscillating means comprising a motor (claim 27);
- The larger of the concentric coils ranges between about 15 and 50 cm (claim 28);
- There are at least three concentric coils, with structure and purpose stated (claim 29);
- The deep lying tissue is the liver and the overlying surface tissue is abdominal tissue (claim 30);
- The applied field coil is on a cylindrical coil form (claim 31);
- The coils are oppositely wound in gradiometer configuration. (claim 32);
- The coil form is non-magnetic, non-metallic material (claim 33);
- The deformable material is water (claim 34); or
- The deformable material is a gel (claim 35).

Independent claim 36 is directed to the magnetic susceptibility detector with an applied field coil configured to create a first zone of a finite magnetic field within a selected region of a specimen, and a second zone of substantially zero magnetic field outside the selected region, the applied field coil having at least two concentric electric current carrying coils, the sensing device having at least one magnetic sensor within the second zone, with the barrier and flexible membrane container being defined. Claims 1, 2, and 5 of the '713 patent do not overlap with the limitations of claim 36.

With respect to the claims depending from claim 36, '713 does not claim, in combination:

- The at least one magnetic sensor is a magnetoresistive sensor (claim 37);
- A flux gate sensor (claim 38);
- A magnetoinductive sensor (claim 39);
- The applied field coil is on a cylindrical coil form (claim 40);
- The coils are oppositely wound in a gradiometer configuration (claim 41);
- The coil form is non-magnetic, non-metallic material (claim 42);
- The deformable material is water (claim 43); or
- The deformable material is a gel (claim 44).

Claim 45 is an independent claim for apparatus for determining magnetic susceptibility variation in body tissue, where the detector has an applied field coil for generating a magnetic field to create a first zone of a finite magnetic field in a selected region of the body, and a second zone of substantially zero magnetic field outside the selected region, the at least one magnetic sensor positioned in the second zone, the detector assembly being connected to oscillating means, the signal generating source, barrier and flexible membrane as before, and means for processing signals from the at least one magnetic sensor of observed magnetic susceptibility variation in the body. The '713 patent simply does not overlap with claim 45.

The subclaims from claim 45 further define, in combination:

- The magnetic sensor attaches to a central region relative to the applied field coil (claim 46);
- The applied field coil is two parallel flat coils and connecting circuit causing current to flow in identical directions at corresponding locations in the two flat coils thereby stimulating uniform sheets of current (claim 47);
- The applied field coil is at least two concentric coils and a connecting circuit causing current to flow in opposite directions to cancel the effects of a magnetic field caused by current flowing through the applied field coil at a central region of the at least two concentric coils (claim 48);

- The detector assembly is multiple stacked applied field coils (claim 49);
- The at least one magnetic sensor is a magnetoresistive sensor as part of a Wheatstone bridge and comprises means for compensating the magnetic sensor for locking an optimal operational state to maintain sensitivity of the apparatus (claim 50);
- A fluxgate sensor (claim 51);
- A magnetoinductive sensor (claim 52);
- The applied field coil comprises a coil on a cylindrical coil form and the at least one magnetic sensor comprises sensor coils axially spaced from the applied field coil (claim 53);
- The sensor coils are oppositely wound in gradiometer configuration (claim 54);
- The coil form is non-magnetic, non-metallic material (claim 55);
- The deformable material is water (claim 56); or
- The deformable material is a gel (claim 57).

Claims 58-60 claim the flexible membrane sealed to a substantially rigid barrier to form a container with deformable material therein having a magnetic susceptibility substantially equivalent to that of body tissue, and having a constant amount of deformable material therein during the measurement process. Sub-claims 59 and 60 respectfully define the deformable material as water and as a gel. There are no claims in the '713 patent which are directed to the fluid bag per se. Thus the double patenting issue cannot apply because the bag is only claimed in '713 in combination with method claim 1.

Claims 61-118 were specifically addressed by the Examiner. For the reasons discussed above with respect to claims 1-60, the double patenting rejection is not applicable and cannot be sustained.

Claims 61-69 are the first group of claims addressed by the Examiner. These are directed to the apparatus as previously discussed with respect to claim 10, but of different scope. The comments with respect to claim 10 apply equally here. The limitations in claim 61 are not mere "obvious alternative variations and groupings" of the '713 claims because they define different

things and do not operate in the same way. More specifically, claim 61 defines the applied field coil and its effects in relation to its structure, which limitations are not in any claims in the '713 patent.

Claims 62-69 further limit and define the invention of claim 61, which do not overlap with the claims of the '713 patent.

Claims 70-78 are another set of apparatus claims having a different scope than any previous claim. The comments set out above apply equally here. More specifically, these claims include an electrostatic shield between the magnetic sensor and the sample to be measured. There is no hint of such claim coverage in the '713 patent.

Sub-claims 71-78 further limit and define the invention of claim 70.

The next set is apparatus claims 79-87. Independent claim 79 specifically defines the magnetic sensor in conjunction with the applied filed coil and with displacement means, all of which are not found in any of the '713 claims.

Sub-claims 80-87 further limit and define the invention of claim 79 and are not mere variations of any '713 claims. More specifically, an electrostatic shield is added in claims 81-87, which has no presence in the '713 claims.

Claims 88-93 are apparatus claims generally patterned after the previously discussed claims. None of the '713 claims are directed to the combination of elements of claim 88, with attention being invited to the definition of the structure of the sensor unit coils in lines 18-21, the relationship of the sensing coils in lines 22-26, and the electrostatic shield in lines 27-28.

Claims 89-93 depend from and further limit and define the invention of claim 88.

Claim 94 is a method claim of a scope that differs from claim 1. There is nothing in the '713 claims that address the step of "scanning the at least one magnetic sensor along the rigid barrier to generate a map of susceptibility variations of the underlying body tissues." This is just one, very clear, difference between the claims in this application and those in the '713 patent.

Method claims 95-99 are directed to the double-modulation technique described on pages 31 and 32 of the specification, with reference to Figs. 13A and 13B. Claim 95 has been amended to more clearly define the process of the double-modulation technique. These changes are not being made for any reason relating to patentability.

There is nothing even remotely similar between the '713 claims and claims 95-99.

Claims 100-105 relate to the apparatus of the invention and include "signal refinement means," which are described on pages 22 and 23 of the specification. There is no equivalent structure and no claim language in the '713 patent that relates in any way to the claim language of claims 100-105.

Apparatus claims 106-114 include the electrostatic shield, which has no equivalence in any '713 claim language.

Finally, apparatus claims 115-118 also include the electrostatic shield, which has no counterpart in the claims of the '713 patent.

In summary, none of the claims in the present application can properly be rejected on the ground of double patenting with respect to the claims of the '713 patent.

The obviousness Rejection Under 35 U.S.C. 103(a)

Claims 61-118 have been rejected under 35 U.S.C. 103(a) as obvious over Paulson et al. in view of Ohyu. Applicants respectfully traverse this rejection.

In the telephone conversation of 2 August 2004, between the undersigned attorney and Examiner Mercader, Ms. Mercader lumped claims 1-60 with claims 61-118 without further comment. Applicants will point out below the deficiencies of the cited references with respect to the claims in the present application.

Claim 1, as amended, clearly defines invention over Paulson and Ohyu. Paulson is a partial example of the conventional water-bag technique, which was described in the background section of the present application. As is well known with cryogenic (SQUID) magnetic measurement systems, because of the extreme delicateness of the sensor, the patient must be moved and the sensor held still in order to make measurements. This greatly limits the frequency of relative movement between sensor and patient. In Paulson, as is known in prior art water bag measurement systems, as the patient moves up and down, the water bag volume changes and water must be moved in and out to maintain the appropriate contact with the contours of the patient's body. Additionally, the sensor and the barrier defining the top of the water bag are maintained stationary and fixed with respect to each other at all times during measurements.

In contradistinction, Applicant's system maintains the water bag, its top defining barrier, and the patient in a constant position, while the sensor moves. Because the sensor moves with respect to the bag top barrier, it can be moved at a much higher frequency than is possible with a variable volume water bag and a moving patient. The volume of the water bag is constant during measurements in the present invention.

Since the water bag volume is fixed and the patient is stationary, Applicant's invention is greatly simplified with respect to the prior art. Applicant's susceptometer measures very small signals. Its purpose is to detect changes in magnetic susceptibilities in a patients' target tissue.

The system of the present invention could not function with a SQUID, which is the type of sensor employed by Paulson, because movement of a SQUID sensor would introduce unacceptable noise. This, in itself, is a significant advantage of the present invention over the prior art.

With regard to Ohyu, the coils of this reference are field-sensing coils only and are not field-producing coils. The coils of Ohyu are not designed to create a zone of nearly zero magnetic field at the common center of the coils, which is a feature of Applicants' coils, as is defined in subsequent claims.

With specific reference again to method claim 1, Applicants agree that Paulson discloses the basic elements of a susceptometer for liver-iron measurements, and it uses a water bag to fill in the space between the patient's body and the instrument. Paulson does not teach or suggest that the distance between the barrier and patient remains substantially constant during the measuring process while the volume of the bag also remains constant, and the instrument moves with respect to the barrier. Since Paulson fails to show or suggest the steps of the method of claim 1, the coil arrangement of Ohyu cannot supply the missing teachings. It is significant that Ohyu employs a SQUID, which could not be used with Applicant's invention. That Ohyu is directed to a SQUID sensor is acknowledged by the Examiner.

Claims 2-9 depend from and serve to further limit and define the invention of claim 1. Specifically, claim 3 relates to displacement of the instrument, which is not possible in Paulson. Claim 5 says the displacement frequency is 0.5 to 10.0 Hz. That is not possible with Paulson.

Independent apparatus claim 10, as amended, similarly defines invention over Paulson. The arguments above with respect to claim 1 apply equally to claim 10. The teachings of Ohyu are not relevant to this claim, which has no language relating to the geometry of the applied field coils.

Claims 11-35 depend from and further define and limit the invention of claim 10. Claim 15 further defines the applied field coil as being configured to provide a first zone of finite magnetic field within a selected region of the patient's body, and a second zone of substantially zero magnetic field outside the selected region, with the magnetic sensor positioned within the second zone. In addition to the deficiencies of Paulson with respect to this claim, Ohyu completely fails to suggest the applied field coil parameters defined in claim 15.

Claims 16-20, 28, 29, 31-33 further define the applied field coil structure. Claim 19 call for the applied field coil to comprise concentric coils. Ohyu discloses coaxial coils, but not concentric coils.

There is no suggestion in Ohyu of the compensating electronics and feedback coil around the magnetic sensor defined in claim 25.

Neither Paulson nor Ohyu suggest any means for oscillating the detector assembly, as defined by claims 26 and 27.

Claims 36-44 are apparatus claims addressed to the magnetic susceptibility detector device. The applied field coil is defined as configured in the manner described in claim 15, creating two magnetic field zones, where the applied field coil has at least two concentric electric current carrying coils, in combination with the water bag and barrier. There is nothing in Paulson or Ohyu upon which to base a finding of obviousness.

Claims 37-44 depend from and serve to further define and limit the invention of claim 36.

Claims 45-57 are apparatus claims addressed to apparatus for determining magnetic susceptibility variations in body tissue. Claim 45 incorporates much of the detector assembly language of claim 36, including the coil configuration generating two magnetic field zones, and adds a means for oscillating the detector assembly, and the signal processing means. Arguments have already been advanced which address the differences between this structure and the cited prior art.

Claims 46-57 further define and limit the invention of claim 45 and are patentable for the reasons previously advanced. Claims 46-49, and 53-55 are further addressed to coil configurations.

Claims 58-60 are addressed to the novel substantially rigid barrier and fluid bag combination. This apparatus is specifically configured to eliminate background tissue response in an instrument for measuring magnetic susceptibility variations in body tissue to determine compositional state in the body. The barrier and the amount of deformable material in the bag remain constant when magnetic susceptibility measurements are being made. Of course, Paulson, and other related prior art, teach that water moves in and out of the bag during the measurement process. This structure and commensurate functions are not disclosed or suggested by either Paulson or Ohyu.

Claim 59 adds that the fluid (deformable material) is water and claim 60 defines it as a gel. The prior art has employed bellows-type water bags, but none have used a gel. Since the prior art has uniformly required that liquid readily and rapidly flow into and out of the bag, a gel could not have been used and most certainly would not have been an obvious variation.

Claims 61-69 relate to apparatus as previously defined, but of different scope. It includes most of the elements of claim 10, and further defines the applied field coil as at least two concentric circular spiral coils. We have previously pointed out that Ohyu does not disclose concentric coils. Fig. 7 of Ohyu, as cited by the Examiner, is a schematic (not physical) depiction and does not indicate concentric coils, only coaxial coils. The physical orientation of those coils (21_0, 21_1, 21_2), are shown in Fig. 4 of Ohyu. The arguments advanced with respect to claim 10 apply equally here.

Claims 62-69 depend from and further define and limit the invention of claim 61. Specifically, there is nothing in Paulson which suggests means for displacing the magnetic sensor and applied field coil simultaneously, to compensate for noise, as defined in claim 62. Claims 63 and 64 further define the displacement distance and frequency, as previously discussed. Claims 65-69 add an electrostatic shield, which is not suggested in Paulson or Ohyu.

Claims 70-78 are apparatus claims of different scope from those previously discussed. Claim 70 includes an electrostatic shield, along with a detector assembly and a substantially rigid barrier and bag. Nothing in the cited prior art responds to this combination.

Claims 71-78 depend from and further define and limit the invention of claim 70. Claims 71 and 72 relate to specifics of the sensing unit and the applied field coil. Claims 73-78 further define the electrostatic shield.

Claims 79-87 are apparatus claims of alternate scope. Claim 79 defines the apparatus as having displacement means for simultaneously displacing the magnetic sensor and the applied field coil, thereby compensating for noise. As discussed previously, there is no teaching in Paulson or Ohyu which could make this claim obvious.

Claims 80-87 depend from and serve to further define and limit the invention of claim 79. The coil structure is addressed in claim 80 and an electrostatic shield is defined in various details in claims 81-87. As stated before, there is no relevant structure in the cited prior art.

Claims 88-93 are further apparatus claims of different scope, addressed to the system. Claim 88 includes the detector assembly, the substantially rigid barrier sealed to the flexible membrane to form a container, as before, and defines the sensor unit as comprising two sensor coils of specified configuration and location, the sensor and applied field coils being mounted together in the sensor unit and having means for displacing the sensor unit to compensate for thermal drift effects, and it has an electrostatic shield. For the reasons stated previously, this claim is free of the cited prior art for several reasons.

Claims 89-93 depend from and further define and limit the invention of claim 80. Claim 89 defines the displacement direction as being toward and away from the body tissue, while claim 90 defines the displacement as being lateral with respect to the body tissue.

Claims 91-93 further define the applied field coil and the sensing coils. The combinations with claim 88 clearly define over the cited prior art.

Claims 94-99 are method claims related to the system for determining magnetic susceptibility variations in selected body tissue of a patient. In addition to the instrument having a magnetic sensor and an applied field coil, and the substantially rigid barrier and flexible bag, this claim includes the step of scanning the sensor along the barrier to generate a map of susceptibility variations in the body tissue. There is no such method combination in the cited prior art, as has been previously discussed.

Claim 95 has been amended to better define the invention, and not for purposed of defining over the prior art. The displacing step has been moved to a more logical position, the moving and repeating steps have been revised to a more clearly define the double-modulation technique previously discussed in the double patenting section above. The last step has been changed to make the terminology consistent. The cited prior art does not suggest a step of displacement of the instrument, much less a double-modulation step.

Claims 96-99 depend and further define and limit the method of claim 95, relating in different ways to the displacing step.

Claims 100-105 are apparatus claims where the detector assembly includes signal refinement means. This means has been discussed above in the double patenting section (see pages 22 and 23 of the specification) and has no counterpart in the cited prior art. Claim 100 also includes the further definition of the applied field coil as producing a region of nearly zero magnetic field with the sensor positioned in that zero field, and includes the advantageous function of the signal refinement means. There is no such structure suggested in the cited prior art.

Claims 101-105 have been corrected to indicate that they are apparatus claims and they further define the signal refinement means.

Claims 106-114 are apparatus claims of still different scope. Claim 106 includes the electrostatic shield in a susceptometer with an alternating applied magnetic field, which is not shown or suggested in the cited prior art. For clarification, Paulson does not suggest putting an electrostatic shield between the detector assembly and the patient. Paulson discloses surrounding the detector assembly with a sheath of vertically oriented copper wires (see 54 in Fig. 2, column 7, line 21-31). The stated purpose of this structure is to act as an RF interference shield and conduct heat upward to the bottom of the liquid helium dewar. Environmental RF interference is a well known problem with SQUID magnetic sensors, so this Paulson structure implies that the sheath of wires is screening out electromagnetic noise from the environment. Applicants' electrostatic shield addresses a different problem, which does not arise in SQUID susceptometers. In order to make very sensitive magnetic susceptibility measurements with sensors that work at room temperature, Applicants' applied magnetic field oscillates as several hundred Hertz. The susceptibility response of liver oscillates at the same frequency. The electrostatic shield shields the patient's body from electric fields which arise due to the passing of AC current through the coils. The shield thereby prevents the creation of electrostatic signals from the body due to the electric field, from corrupting the signal at the sensor. Additionally, the use of an AC applied field permits the detector assembly to be

moved with respect to the patient without generating interfering signals due to the motion of the magnetic sensors with respect to the ambient magnetic field.

Claims 107-114 depend from and further define and limit the invention of claim 106. Claim 107 and 108 relate to the structure of the sensing and applied field coils, and claim 109-114 further define the electrostatic shield.

Claims 115-118 are apparatus claims of still different scope. Claim 115 defines the sensing coils of the sensing unit, the relationship between the sensing coils and the applied field coil, which coils are mounted together on the sensor unit which has displacement means to compensate for temperature drift, and includes an electrostatic shield. This combination is clear of the cited prior art for the many reasons advanced above.

Claims 116-118 further define and limit the invention of claim 115, defining the two different types of displacement motion in claim 116 and 117, and further defining the coil structures in claim 118.

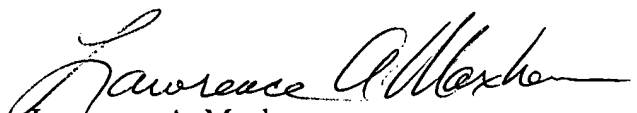
CONCLUSION

In view of the above discussion, it is respectfully requested that the rejections be reconsidered and that they be withdrawn.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Should any issues remain, Examiner Mercader is invited to telephone the undersigned attorney.

Respectfully submitted,

WILLIAM F. AVRIN ET AL.



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